K040342

APR 1 3 2004

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to § 513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation has chosen to submit a summary of information respecting safety and effectiveness. According to § 513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed **IDC System** is as follows:

Common Name Arterial Embolization Device

Trade Name Interlocking Detachable Coil System (IDC)

Device Classification Name Arterial Embolization Device
Product Code – 74KRD
Regulation Number – 870.3300

Device Classification Class III

Device Panel Cardiovascular

Performance Standards No formal performance standards have been established by the Food and Drug Administration for this device.

Predicate Devices The predicate devices are listed in the table below.

Table 3

Device	Company	510(k) Number/ Concurrence Date
Coil Pusher Boston Scientific Target		K911779 K914786
Coil Pusher – 16 Boston Scientific Target		K891688
GDC Coil Boston Scientific Target		
Occlusion Coils Boston Scientific Target		K914786 K901721 K911779 K891688

All of the devices mentioned above have been determined substantially equivalent by FDA

Device Description The Boston Scientific IDC System is manufactured from platinum and comes attached to an Interlocking Coil Pusher. It is designed to be delivered under fluoroscopy using a .018" compatible microcatheter with two radiopaque tip makers. The interlocking design allows the coil to be advanced and retracted before final placement in the vessel, thus aiding in precise, controlled delivery.

Safety and Performance:

Functional and integrity bench testing and Biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memorandum #G95-1, May 1, 1995, Use of International Standard ISO-10993, *"Biological Evaluation of Medical Devices Part 1: Evalution and Testing"* were performed, and the data supported the substantial equivalence of the **IDC System** to the predicate devices.

Conclusion:

Based on the Indictions for Use, technical characteristics testing the IDC System has been show to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 3 2004

Boston Scientific Corporation
c/o Mr. Arthur Friedman
Vice President, Regulatory Affiars
One Boston Scientific Place
Natick, MA 01760

Re: K040342
Interlocking Detachable Coil System (IDC System)
Regulation Number: 21 CFR 870.3300
Regulation Name: Embolization Arterial Device
Regulatory Class: III (three)
Product Code: KRD
Dated: February 5, 2004
Received: February 12, 2004

Dear Mr. Friedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Volkmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040342

Device Name: Interlocking Detachable Coil System (IDC System)

Indications For Use:

The IDC System is indicted to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richmond
Division Sign-Off)
Division of **Cardiovascular Devices**

510(k) Number K040342